

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

Date of mailing (day/month/year) 18 April 2001 (18.04.01)	To: Commissioner US Department of Commerce United States Patent and Trademark Office, PCT 2011 South Clark Place Room CP2/5C24 Arlington, VA 22202 ETATS-UNIS D'AMERIQUE in its capacity as elected Office
International application No. PCT/US00/19558	Applicant's or agent's file reference X-12636
International filing date (day/month/year) 02 August 2000 (02.08.00)	Priority date (day/month/year) 12 August 1999 (12.08.99)
Applicant THOMPSON, William, Webster et al	

1. The designated Office is hereby notified of its election made:

in the demand filed with the International Preliminary Examining Authority on:

14 February 2001 (14.02.01)

in a notice effecting later election filed with the International Bureau on:

2. The election was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Zakaria EL KHODARY Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

RECEIVED

To:
NOV 30 2001
DEMETER John C.
ELI LILLY AND COMPANY & COMPANY
Lilly Corporate Center PATENT DIVISION
Indianapolis, Indiana 46285
ETATS-UNIS D'AMERIQUE

PCTNOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing (day/month/year)	12.11.2001
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Applicant's or agent's file reference X-12636	IMPORTANT NOTIFICATION	
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International application No. PCT/US00/19558	International filing date (day/month/year) 02/08/2000	Priority date (day/month/year) 12/08/1999
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Applicant ELI LILLY AND COMPANY et al.
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1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
---------------------------------------	--------------------

European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Name and mailing address of the IPEA/	Authorized officer
---------------------------------------	--------------------

Gallego, A
Tel. +49 89 2399-8102



PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference X-12636	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US00/19558	International filing date (day/month/year) 02/08/2000	Priority date (day/month/year) 12/08/1999	
International Patent Classification (IPC) or national classification and IPC A01N43/22			
Applicant ELI LILLY AND COMPANY et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I Basis of the report
- II Priority
- III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV Lack of unity of invention
- V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI Certain documents cited
- VII Certain defects in the international application
- VIII Certain observations on the international application

Date of submission of the demand 14/02/2001	Date of completion of this report 12.11.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Krattinger, B Telephone No. +49 89 2399 8550



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/19558

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):
Description, pages:

1-25 as originally filed

Claims, No.:

1-15 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/19558

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims 1-15
	No: Claims
Inventive step (IS)	Yes: Claims
	No: Claims 1-15
Industrial applicability (IA)	Yes: Claims 1-11, 14, 15 : yes ; 12-13 : no opinion (see section VIII)
	No: Claims

2. Citations and explanations
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/19558

Re Item V

The present application concerns a ectoparasidicidal suspension formulation containing a spinosyn (claims 1-9, 15), a article of manufacture containing said formulation (claim 10), a method of manufacturing the formulation (claim 11), a method of controlling an ectoparasite infestation (claims 12-13), the use of the formulation for the preparation of a medication (claim 14).

Reference is made to the following documents:

- D1: EP-A-0 375 316, same family as US-A-5 571 901 which is cited in the application
- D2: GB-A-2 088 212
- D3: WO 82 02647 A)
- D4: [Online] 12 June 1988 (1988-06-12) Retrieved from the Internet:
<URL:<http://www.chemsoc.org/chempest/html/2A-0024.html>> [retrieved on 2000-11-17]

Novelty

1. the spinosyn/dispersant weight ratio of compositions disclosed in D1 does not fall within the range 3/1 to 1/5 but is higher.
2. The compositions disclosed in D2 do not contain spinosyn but pyrethroid derivatives.
3. The compositions disclosed in D3 do not contain spinosyn.
4. Document D4 does not refer to aqueous compositions or to dispersant.
5. Therefore in view of what is said above, the presently claimed matter is novel (Art. 33(2) PCT).

Inventive Step

Document D1, which is considered as closest prior art, discloses aqueous

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/19558

compositions (suspension) of spinosyn which differ from the presently claimed matter by the ratio spinosyn/dispersant (D1 : examples 12.A and 13.C).

In view of the content of that document, the problem to be solved by the present application is the provision of alternative aqueous suspensions of spinosyn to be used for controlling ectoparasites on animal.

The presently claimed solution consists of an aqueous suspension formulation containing spinosyn milled to an average size of about 1 to about 15 micron, a surfactant and a dispersant wherein the spinosyn/dispersant weight ratio is from 3/1 to 1/5.

The presently claimed compositions contain the same ingredients as the compositions 12.A and 13C of D1 but in different ratio (Example 12.A ratio 12.5/1; example 13.C ratio 6/1).

Since the claimed ratio spinosyn/dispersant does not seem to involve any particular surprising effect or advantage in comparison with the composition of D1 (ex. 12.A and 13.C), the presently claimed matter is considered to be analogous to said compositions. Hence the presently claimed matter does not involve an inventive step (Art. 33(3) PCT).

When the present application will enter the European Regional Phase, the Applicant will be invited to provide argumentation or evidence that the presently claimed compositions show advantages or surprising effects when they are compared with the compositions of the prior art D1 12A and 13C. If the Applicant wishes to provide comparative tests, compositions containing the same ingredients as the compositions 12A and 13C could be used.

Re Item VIII

1. Claims 12 and 13 define a method of controlling an ectoparasite on an animal. This is considered as a therapeutical treatment. Hence claim 12 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

For the assessment of the present claims 12 and 13 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO,

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/19558

for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

2. Claim 15 is not acceptable because it refers to the description (Rule 6.2.a PCT and Gazette PCT III.4.10).
3. No clear support in the description, but only a partial support can be found in the description on page 3, lines 6-10 for the subject matter of claim 9. The Applicant is invited to name any possible support for the subject matter of said claim. If no support can be found, then a support should be added in the description (Art. 6 PCT).
4. A discrepancy appears between the subject matter of claim 10 and its supportive counterpart in the description. Claim 10 defines an article containing the formulations of claims 1 to 9, whereas the description discloses on page 11, lines 24-31 an article containing only the formulation of claim 1.
5. A discrepancy appears between the subject matter of claim 12 and its supportive counterpart in the description. Claim 12 defines a method involving the formulations of claims 1 to 9, whereas the description discloses on page 11, lines 24-31 a method involving only the formulation of claim 1.
6. The same remark as above applies to claim 14.
7. A discrepancy appears between the subject matter of claim 13 and its supportive counterpart in the description on page 12, lines 23-27 that the treated area is less than 10% of the surface area of the air and skin of the animal, whereas the claim does not contain that feature.
8. When the present application will enter the European Regional Phase, the Applicant will be invited to remove the discrepancies defined in points 4-7 either by amending the claims, either by amending the description to render the claims supported by the description (Art. 6 PCT).

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/19558

PATENT COOPERATION TREATY

10/048239

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference X-12636	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US 00/ 19558	International filing date (<i>day/month/year</i>) 02/08/2000	(Earliest) Priority Date (<i>day/month/year</i>) 12/08/1999
Applicant ELI LILLY AND COMPANY et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.
 It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
 - a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
 - b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :
 - contained in the international application in written form.
 - filed together with the international application in computer readable form.
 - furnished subsequently to this Authority in written form.
 - furnished subsequently to this Authority in computer readable form.
 - the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished
2. **Certain claims were found unsearchable** (See Box I).
3. **Unity of invention is lacking** (see Box II).
4. With regard to the **title**,
 - the text is approved as submitted by the applicant.
 - the text has been established by this Authority to read as follows:
ECTOPARASITICIDAL AQUEOUS SUSPENSION FORMULATIONS OF SPINOSYNS
5. With regard to the **abstract**,
 - the text is approved as submitted by the applicant.
 - the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. The figure of the **drawings** to be published with the abstract is Figure No.
 - as suggested by the applicant.
 - because the applicant failed to suggest a figure.
 - because this figure better characterizes the invention. None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/19558

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A01N43/22 // (A01N43/22, 25:04)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, EPO-Internal, BIOSIS, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 375 316 A (LILLY CO ELI) 27 June 1990 (1990-06-27) page 3, line 14 – line 19 page 17, line 50 – line 52 page 37, line 14 – line 17 page 37, line 28 – line 34 page 45, line 1 – line 4 page 46, line 6 – line 11 page 55, line 40 – line 48 page 56, line 27 – line 35 page 56, line 48 – line 52 ---- -/-/	1-15

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

20 November 2000

Date of mailing of the international search report

30/11/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Lamers, W

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 00/19558

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	J.WINKLE ET AL.: "RHEOLOGICAL STUDIES ON SUSPENSION CONCENTRATES" RHEOLOGICAL STUDIES ON SUSPENSION CONCENTRATES OF SPINOSAD, 'Online! 12 June 1988 (1988-06-12), XP002153298 Retrieved from the Internet: <URL: http://www.chemsoc.org/chempest/html/2A-0024.html > 'retrieved on 2000-11-17! abstract ----	1-15
A	GB 2 088 212 A (WELLCOME FOUND) 9 June 1982 (1982-06-09) page 3, line 27 - line 30 page 16; example 10 ----	1-15
A	WO 82 02647 A (WELLCOME FOUND) 19 August 1982 (1982-08-19) page 2, paragraph 2 -page 3, paragraph 3 -----	1-18

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/19558

Patent document cited in search report		Publication date	Patent family member(s)	Publication date	
EP 0375316	A	27-06-1990	AT 116325 T AU 624458 B AU 4689189 A BG 60520 B BR 1100144 A BR 8906547 A CA 2005784 A,C CN 1043742 A,B CZ 8907170 A DD 290351 A DE 68920301 D DK 642089 A EG 19191 A ES 2065398 T FI 95601 B FI 96224 B GR 3015598 T HU 52562 A,B IE 65919 B IL 92743 A IN 169756 A JP 2223589 A JP 2535080 B KR 143566 B MX 18755 A NO 176914 B NZ 231831 A OA 9249 A PT 92607 A,B RO 106065 B TR 26146 A US 5496931 A US 5571901 A YU 239389 A ZA 8909680 A AU 631693 B AU 6641490 A BR 9006982 A EP 0454820 A JP 5504469 T WO 9106552 A US 5362634 A	15-01-1995 11-06-1992 21-06-1990 28-07-1995 28-03-2000 04-09-1990 19-06-1990 11-07-1990 11-08-1999 29-05-1991 09-02-1995 20-06-1990 29-09-1994 16-02-1995 15-11-1995 15-02-1996 30-06-1995 28-07-1990 29-11-1995 21-10-1994 21-12-1991 05-09-1990 18-09-1996 15-07-1998 31-01-1994 13-03-1995 26-10-1994 30-06-1992 29-06-1990 26-02-1993 15-02-1995 05-03-1996 05-11-1996 30-04-1991 26-09-1990 03-12-1992 31-05-1991 24-12-1991 06-11-1991 15-07-1993 16-05-1991 08-11-1994	
GB 2088212	A	09-06-1982	FR 2494561 A GB 2150025 A,B GB 2150026 A,B IE 52109 B IE 52110 B IE 52108 B NZ 199009 A NZ 205945 A NZ 205946 A US 5286749 A ZA 8108079 A ZA 8303066 A	28-05-1982 26-06-1985 26-06-1985 24-06-1987 24-06-1987 24-06-1987 24-01-1986 30-09-1987 30-09-1987 15-02-1994 27-07-1983 27-07-1983	
WO 8202647	A	19-08-1982	AU 8083282 A BR 8206159 A	26-08-1982 11-01-1983	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 00/19558

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 8202647 A		EP 0070852 A JP 58500024 T ZA 8200453 A ZW 1682 A	09-02-1983 06-01-1983 29-12-1982 31-08-1983

10/048239

PATENT COOPERATION TREATY

REC'D 14 NOV 2001

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference X-12636	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US00/19558	International filing date (day/month/year) 02/08/2000	Priority date (day/month/year) 12/08/1999
International Patent Classification (IPC) or national classification and IPC A01N43/22		
<p>Applicant ELI LILLY AND COMPANY et al.</p> <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application 		

Date of submission of the demand 14/02/2001	Date of completion of this report 12.11.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Krattinger, B Telephone No. +49 89 2399 8550



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/19558

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-25 as originally filed

Claims, No.:

1-15 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

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5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US00/19558

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims 1-15
	No: Claims
Inventive step (IS)	Yes: Claims
	No: Claims 1-15
Industrial applicability (IA)	Yes: Claims 1-11, 14, 15 : yes ; 12-13 : no opinion (see section VIII)
	No: Claims

2. Citations and explanations
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/19558

Re Item V

The present application concerns a ectoparasidicidal suspension formulation containing a spinosyn (claims 1-9, 15), a article of manufacture containing said formulation (claim 10), a method of manufacturing the formulation (claim 11), a method of controlling an ectoparasite infestation (claims 12-13), the use of the formulation for the preparation of a medication (claim 14).

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Novelty

1. the spinosyn/dispersant weight ratio of compositions disclosed in D1 does not fall within the range 3/1 to 1/5 but is higher.
2. The compositions disclosed in D2 do not contain spinosyn but pyrethroid derivatives.
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4. Document D4 does not refer to aqueous compositions or to dispersant.
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Inventive Step

Document D1, which is considered as closest prior art, discloses aqueous

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US00/19558

compositions (suspension) of spinosyn which differ from the presently claimed matter by the ratio spinosyn/dispersant (D1 : examples 12.A and 13.C).

In view of the content of that document, the problem to be solved by the present application is the provision of alternative aqueous suspensions of spinosyn to be used for controlling ectoparasites on animal.

The presently claimed solution consists of an aqueous suspension formulation containing spinosyn milled to an average size of about 1 to about 15 micron, a surfactant and a dispersant wherein the spinosyn/dispersant weight ratio is from 3/1 to 1/5.

The presently claimed compositions contain the same ingredients as the compositions 12.A and 13C of D1 but in different ratio (Example 12.A ratio 12.5/1; example 13.C ratio 6/1).

Since the claimed ratio spinosyn/dispersant does not seem to involve any particular surprising effect or advantage in comparison with the composition of D1 (ex. 12.A and 13.C), the presently claimed matter is considered to be analogous to said compositions. Hence the presently claimed matter does not involve an inventive step (Art. 33(3) PCT).

When the present application will enter the European Regional Phase, the Applicant will be invited to provide argumentation or evidence that the presently claimed compositions show advantages or surprising effects when they are compared with the compositions of the prior art D1 12A and 13C. If the Applicant wishes to provide comparative tests, compositions containing the same ingredients as the compositions 12A and 13C could be used.

Re Item VIII

1. Claims 12 and 13 define a method of controlling an ectoparasite on an animal. This is considered as a therapeutical treatment. Hence claim 12 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

For the assessment of the present claims 12 and 13 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO,

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for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

2. Claim 15 is not acceptable because it refers to the description (Rule 6.2.a PCT and Gazette PCT III.4.10).
3. No clear support in the description, but only a partial support can be found in the description on page 3, lines 6-10 for the subject matter of claim 9. The Applicant is invited to name any possible support for the subject matter of said claim. If no support can be found, then a support should be added in the description (Art. 6 PCT).
4. A discrepancy appears between the subject matter of claim 10 and its supportive counterpart in the description. Claim 10 defines an article containing the formulations of claims 1 to 9, whereas the description discloses on page 11, lines 24-31 an article containing only the formulation of claim 1.
5. A discrepancy appears between the subject matter of claim 12 and its supportive counterpart in the description. Claim 12 defines a method involving the formulations of claims 1 to 9, whereas the description discloses on page 11, lines 24-31 a method involving only the formulation of claim 1.
6. The same remark as above applies to claim 14.
7. A discrepancy appears between the subject matter of claim 13 and its supportive counterpart in the description on page 12, lines 23-27 that the treated area is less than 10% of the surface area of the air and skin of the animal, whereas the claim does not contain that feature.
8. When the present application will enter the European Regional Phase, the Applicant will be invited to remove the discrepancies defined in points 4-7 either by amending the claims, either by amending the description to render the claims supported by the description (Art. 6 PCT).

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